DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 27, 2015

Arc Surgicals Manufacturing LLC.
Craig Pagan
Consultant
1135 W Nasa Blvd Ste 500
Melbourne, Florida 32901

Re: K141559
Trade/Device Name: V-guide for Ventriculostomies
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: June 10, 2014
Received: June 12, 2014

Dear Craig Pagan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141559

Device Name
V-Guide for Ventriculostomies

Indications for Use *(Describe)*
The V-Guide is designed to be used for frontal placement of an intraventricular catheter during a ventriculostomy. The device is for use with intraventricular catheters

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

(1) **Submitter's name, address, telephone number, a contact person and date summary was prepared:**

ARC Surgicals Manufacturing LLC
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Orlando, FL 32826
Tel: 407-203-9590
Contact: Habeel Gazi, Director
Email: habeel@arcsurgicals.com
Date Prepared: June 9, 2014

(2) **Name(s) of device:**

Proprietary/Trade Name:	V-Guide for Ventriculostomies
Common Name:	Neurological stereotaxic instrument
Classification Name:	Stereotaxic Instrument
Classification Panel	Neurology
Product Code:	HAW
Regulatory Class:	II
Regulation Number	21 CFR 882.4560

(3) **Legally Marked Predicate Device to which the submitter claims substantial equivalence:**

Arc Surgical Manufacturing's V-Guide for Ventriculostomies is substantially equivalent to the Sparta Instrument Corporation's Ghajar Intraventricular Catheter Guide – K854475.

(4) **Description of device(s):**

V-Guide for Ventriculostomies (Reorder # 7000)

The V-Guide is a sterile, single use, Neurological Stereotactic Instrument that provides the surgeon with a localized reference guide for performing Ventriculostomies. The device is compatible with 3.3mm ventricular catheters. The device consists of a Base Assembly, three Impression Pins (16 Gauge Stainless Steel needles with aluminum hubs) that act as legs for the Base, a Pierce Sagittal assembly and a Pierce Barrel.

The device allows the user to orient the sagittal plane to 0º and the lateral plane to 0º. This aligns the device to a perpendicular track to the entry point. A standard 3.3mm catheter is then passed through the guide into the brain at the predetermined distance

as in a standard Ventriculostomy. If the flow of cerebrospinal fluid is noted and the surgeon is satisfied the position of the catheter, the V-guide can be removed from the catheter by removing the barrel. If the surgeon is not satisfied with the position of the catheter, the catheter is removed and this technique can be repeated with different angles to allow for an objective change in direction of the catheters angle to the cranium.

(5) **Indications for Use:**

The V-Guide is designed to be used for frontal placement of an intraventricular catheter during a ventriculostomy. The device is for use with intraventricular catheters.

(6) **Comparison of Technological Characteristics to Predicate Device:**

The V-Guide for Ventriculostomies has the same technological characteristics as the predicate device, the Ghajar Guide (K854475) as described below:

- devices are designed to guide catheters for Ventriculostomies
- devices have 3 legs that position the device over the burr hole
- devices are designed to place catheters at 90º (perpendicular) to the skull
- devices are visually placed over the burr hole
- devices are hand held during insertion of the catheter
- both devices are made of plastic material

Differences:

The main difference between the V-Guide and the predicate Ghajar Guide is that the V-Guide allows the user to make objective changes in the direction of the catheters angle to the cranium.

Substantial Equivalence Comparison

Product Information	V-Guide This submission	Ghajar Intraventricular Catheter Guide	Similarities and Differences
FDA Classification	Class II	Class II	Same
Regulation Number	21 CFR 882.4560	21 CFR 882.4560	Same
Product Code	HAW	HAW	Same
Indications for Use	The V-Guide is designed to be used for frontal placement of an intraventricular catheter during a ventriculostomy. The device is for use with intraventricular catheters.	The Ghajar Guide is designed to be used as a device for anterior placement of an intraventricular catheter at ninety degrees to the skull surface.	Both devices are indicated for frontal or anterior placement of intraventricular catheters. The Ghajar Guide is only indicated for placement at 90 degrees to the skull

Product Information	V-Guide This submission	Ghajar Intraventricular Catheter Guide	Similarities and Differences
			surface, whereas the V Guide allows the physician make objective changes in the direction of the catheters angle to the skull.
Catheter Compatibility	3.3mm	1.30 – 3.25mm	V-Guide is compatible with one size catheter - 3.3mm OD whereas the Ghajar Guide is compatible with catheter from 1.30 – 3.25mm OD.
Materials	ABS with Stainless Steel Legs (See note 1)	Plastic	The bodies of both devices are the same - plastic. The Legs of the V Guide are made of stainless steel rather than plastic. Comparative testing shows comparable performance.
Accuracy	± 3mm at 6cm target depth	Unknown	Same – based on bench test data the V Guide was comparable to the Ghajar guide.
Sterilization Method	Gamma	Ethylene Oxide	Sterilization process is different, but SAL 10^{-6} is the same.
Single Use	Yes	Yes	Same
Packaging	PETG Tray with Tyvek lid	PETG Tray with Tyvek lid	Same

Note 1: Biocompatibility of the Stainless Steel Legs was established based on the Covidien product # 8881200052 Monoject™ Standard Hypodermic Needle, Aluminum Hub, 16 G x 1" (1.651 mm x 2.5 cm) A. The FDA classifies this product is a class II device, which is cleared under 510k K854547.

(7) **Performance Data:**

The following nonclinical testing was performed in order to evaluate the substantial equivalence of the V-Guide to the predicate device:

- Accuracy Testing at 90° - at 90º (Sagittal angle adjustment set at 0 and Lateral Angle (Barrel) set at 0) the V-Guide will be accurate to ± 3.0mm with a target depth of 6 cm.

This test verified the accuracy of the device using a bench model with a target at 6 cm depth. The accuracy of the V-Guide was compared to the predicate device (Ghajar Guide) using the same bench model. The results of the tests shows that the V-Guide is comparable to the accuracy of the predicate device.

(8) **Conclusions:**

Based on the non-clinical performance data performed comparing the Arc Surgicals Manufacturing V-Guide to the predicate device, it is concluded that the data supports the safety of the device and the hardware verification demonstrate that the V-Guide device should perform as intended in the specified use conditions. The data demonstrate that the V-Guide device performs comparably to the predicate device that is currently marketed for the same intended use.